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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,449	03/15/2004	Lee-Hwei K. Sun	03SUN2001-B	2195

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Mr. Hsiang-ning Sun
Ths SUN Law Office PLLC
4212 Villanova Street
Houston, TX 77005-3529

EXAMINER

KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/800,449

Applicant(s)

SUN ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 11 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/10/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The information disclosure statement of 10 December 2004 has been received and considered.

Claims 1-11 are pending and under examination.

Claim Objections

Claims 1 and 6 are objected to because of the following informalities: Claim 1 contains a typographical error in the fourth line, "mutations mutation." It is suggested that the claim be amended to delete the second word, "mutation." In claim 6, the word "its" has been lined through as if to indicate that it is deleted. However, the claim has not been identified as having been amended, and thus it is unclear if this was intentional. Applicant's attention is directed to 37 C.F.R. § 1.121(c), which states, "In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently Amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered). Appropriate correction is required.

Claims 2-5 and 7-9 are objected to as being dependent upon a base claim which is objected to for informalities, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, avoiding the informalities mentioned above.

Drawings

The drawings are objected to because there are several sheets having the same Figure numbers. For example, there are two sheets labeled Figure 2A, two sheets labeled Figure 2B, and two sheets labeled Figure 2C. It is suggested that Applicant submit copies of the formal drawings submitted in the parent application, 09/968,362, on 26 July 2004.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Allowable Subject Matter

The claims are free of the prior art. The closest prior art includes U.S. Patent 5,876,969 to Fleer et al. and U.S. Patent 6,291,661 B1 to Graddis et al.

'969 teaches a recombinant hG-CSF-L-HSA fusion protein comprising hG-CSF, a peptide linker and a heterologous protein, HSA (col. 18-20, Example 9). The linker is four Glycine residues, meeting the linker limitations in claim 2 (col. 18, li. 67 "HSA-Gly₄-G-CSF"). '969 teaches that such chimeric molecules have greater stability and longer serum half-life than the native ligand unattached to HSA (col. 1, li. 52-58; col. 22-24). '969 also teaches CHO cells as the host cell line (col. 3, li. 45-49), and methods of recombinantly producing the fusion protein (col. 4, li. 24-42, for example).

'969 does not teach the fusion protein wherein a human IgG Fc variant is used instead of HSA.

'661 teaches a fusion protein of flt3 to a domain of the Fc portion of IgG, which improves stability and half-life of the fusion protein relative to flt3 alone (col. 12, li. 7-14; col. 5, li. 26-28). However, the particular IgG Fc variant defined in the claims (i.e., comprising SEQ ID NO: 20) is not disclosed or suggested in the prior art. Therefore, the claimed invention is not obvious.

Furthermore, since IgG fusions of cytokines are known in the art to be highly active and have longer serum half lives, (e.g., as in '969), the invention meets the requirements of 35 U.S.C. § 112, first paragraph, regarding enablement.

Conclusion

Claims 10 and 11 are allowable. Claims 1-9 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C. Kemmerer

ECK

ELIZABETH KEMMERER
PRIMARY EXAMINER